# **Complete Summary**

#### **GUIDELINE TITLE**

Endometrial ablation.

# **BIBLIOGRAPHIC SOURCE(S)**

American College of Obstetricians and Gynecologists (ACOG). Endometrial ablation. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2007 May. 16 p. (ACOG practice bulletin; no. 81). [79 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

# **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

### SCOPE

# **DISEASE/CONDITION(S)**

Abnormal uterine bleeding (menorrhagia)

# **GUIDELINE CATEGORY**

Evaluation Treatment

**DISCLAIMER** 

#### **CLINICAL SPECIALTY**

Obstetrics and Gynecology Surgery

#### **INTENDED USERS**

Physicians

# **GUIDELINE OBJECTIVE(S)**

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review the efficacy, safety, indications, and limitations of techniques for endometrial ablation

#### **TARGET POPULATION**

Pre- or postmenopausal women with abnormal uterine bleeding

## INTERVENTIONS AND PRACTICES CONSIDERED

## **Surgical Endometrial Ablation**

- 1. Laser and resectoscopic endometrial ablation
- 2. Nonresectoscopic endometrial ablation
  - Cryotherapy
  - Heated free fluid
  - Microwaves
  - Radiofrequency electricity
  - Thermal balloon
- 3. Endometrial sampling and review of endometrial histopathological results before surgery
- 4. Counseling of women to use contraception following endometrial ablation
- 5. Performance of resectoscopic endometrial ablation with laparoscopic monitoring
- 6. Use of fluid management and monitoring system during resectoscopic endometrial ablation
- 7. Anesthesia use during endometrial ablation
- 8. Endometrial ablation in the presence of uterine leiomyomata

#### **MAJOR OUTCOMES CONSIDERED**

- Patient satisfaction
- Bleeding outcome
- Rates of complications
- · Rates of repeated procedures and hysterectomies
- Duration of hospitalization

# METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and October 2006. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

#### **NUMBER OF SOURCE DOCUMENTS**

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- **I** Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1** Evidence obtained from well-designed controlled trials without randomization.
- **II-2** Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3** Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III** Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

# METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

# **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician—gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- **Level C** Recommendations are based primarily on consensus and expert opinion.

# **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

# **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

## **RECOMMENDATIONS**

#### **MAJOR RECOMMENDATIONS**

The grades of evidence (I-III) and levels of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

# The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

- For women with normal endometrial cavities, resectoscopic endometrial ablation and nonresectoscopic endometrial ablation systems appear to be equivalent with respect to successful reduction in menstrual flow and patient satisfaction at 1 year following index surgery.
- Resectoscopic endometrial ablation is associated with a high degree of patient satisfaction but not as high as hysterectomy.

# The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B):

- Hysterectomy rates associated with both resectoscopic endometrial ablation and nonresectoscopic endometrial ablation are at least 24% within 4 years following the procedure.
- Women undergoing endometrial ablation with previous or concomitant laparoscopic sterilization are at low risk for the development of cyclic or intermittent pelvic pain subsequent to the procedure.
- Patient satisfaction and reduction in menstrual blood flow after endometrial ablation in women with normal endometrial cavities is similar to that experienced by women using the levonorgestrel-secreting intrauterine system.

# The following recommendations and conclusions are based primarily on consensus and expert opinion (Level C):

- Patients who choose endometrial ablation should be willing to accept normalization of menstrual flow, not necessarily amenorrhea, as an outcome.
- Premenopausal patients undergoing endometrial ablation should be counseled to use appropriate contraception.
- Nonresectoscope endometrial ablation is not recommended in women with endometrial cavities that exceed device limitations.
- The endometrium of all candidates for endometrial ablation should be sampled, and histopathologic results should be reviewed before the procedure.
- Women with endometrial hyperplasia or uterine cancer should not undergo endometrial ablation.
- Performance of nonresectoscopic endometrial ablation in patients with prior classic cesarean delivery or transmural myomectomy may increase the risk of damage to surrounding structures. If endometrial ablation is to be performed in such patients, it may be best to perform resectoscopic endometrial ablation with laparoscopic monitoring. Safety of nonresectoscopic endometrial ablation in women with low transverse cesarean delivery has not been adequately studied.
- For resectoscopic endometrial ablation, it is recommended that a fluid management and monitoring system that provides "real-time" output of fluid balance be used.

# **Definitions:**

#### **Grades of Evidence**

- I Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1** Evidence obtained from well-designed controlled trials without randomization.
- **II-2** Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3** Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III** Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

### **Levels of Recommendation**

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- **Level C** Recommendations are based primarily on consensus and expert opinion.

# **CLINICAL ALGORITHM(S)**

None provided

#### **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### **POTENTIAL BENEFITS**

Appropriate use of endometrial ablation

### **POTENTIAL HARMS**

- Fluid overload (resectoscopic only)
- Electrolyte disturbances (resectoscopic only)
- Bleeding
- Injury to the cervix and vagina
- Uterine perforation with potential damage to surrounding structures
- Postprocedural infection
- Unintended pregnancy
- Malignancy
- Pain associated with prior or concomitant tubal ligation

### **CONTRAINDICATIONS**

#### **CONTRAINDICATIONS**

- Endometrial ablation should not be performed with recent pregnancy or in the presence of active or recent uterine infection, endometrial malignancy, or hyperplasia.
- All of the currently available nonresectoscopic endometrial ablation devices have limitations with respect to the size of the endometrial cavity and the nature and extent of anatomic distortion of the endometrial surface.
   Consequently, they are not recommended for use in women with endometrial cavities that exceed device limitations. Similar circumstances apply for resectoscopic endometrial ablation as well, but the manual nature of the technique may allow it to be applied to a wider spectrum of endometrial cavity sizes and configurations. Indeed, there is evidence that, at least in experienced and able hands, success rates in uteri greater than 12 gestational weeks in size may be equivalent to that of women with smaller sized uteri. Table 3 in the original guideline document demonstrates parameters such as the current limitations in both minimum- and maximum-sounded length and for the type and diameter of submucosal leiomyomata for the nonresectoscopic endometrial ablation devices currently available in the United States.
- Additional relevant and absolute contraindications are discussed in the original guideline document.

# **QUALIFYING STATEMENTS**

# **QUALIFYING STATEMENTS**

- These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.
- The process of informed consent for endometrial ablation should include device- or system-appropriate information regarding risk and a realistic discussion of the potential outcomes of surgery because amenorrhea is not achieved in a substantial number of cases. Furthermore, given the persistence of endometrial tissue, premenopausal patients undergoing endometrial ablation should be counseled to use appropriate contraception.

### **IMPLEMENTATION OF THE GUIDELINE**

#### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

#### **IMPLEMENTATION TOOLS**

Audit Criteria/Indicators Foreign Language Translations Patient Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

**Getting Better** 

#### **IOM DOMAIN**

Effectiveness Patient-centeredness

# **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

American College of Obstetricians and Gynecologists (ACOG). Endometrial ablation. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2007 May. 16 p. (ACOG practice bulletin; no. 81). [79 references]

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### **DATE RELEASED**

2007 May

#### **GUIDELINE DEVELOPER(S)**

American College of Obstetricians and Gynecologists - Medical Specialty Society

# **SOURCE(S) OF FUNDING**

American College of Obstetricians and Gynecologists (ACOG)

#### **GUIDELINE COMMITTEE**

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

#### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Not stated

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: <a href="mailto:sales@acog.org">sales@acog.org</a>. The ACOG Bookstore is available online at the ACOG Web site.

#### **AVAILABILITY OF COMPANION DOCUMENTS**

Proposed performance measures are included in the original guideline document.

#### **PATIENT RESOURCES**

The following is available:

• Endometrial ablation. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2000.

Electronic copies: Available from the <u>American College of Obstetricians and Gynecologists (ACOG) Web site</u>. Copies are also available in Spanish.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: <a href="mailto:sales@acog.org">sales@acog.org</a>. The ACOG Bookstore is available online at the ACOG Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material

and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

#### **NGC STATUS**

This NGC summary was completed by ECRI Institute on October 5, 2007. The information was verified by the guideline developer on December 3, 2007.

#### **COPYRIGHT STATEMENT**

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

#### **DISCLAIMER**

#### NGC DISCLAIMER

The National Guideline Clearinghouse<sup>™</sup> (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <a href="http://www.guideline.gov/about/inclusion.aspx">http://www.guideline.gov/about/inclusion.aspx</a>.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 9/15/2008

